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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,839	06/15/2000	James Anthony	2629-4017	3097

7590

04/10/2002

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/594,839

Applicant(s)

ANTHONY ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 13) filed on January 9, 2002 has been entered.
2. The Information Disclosure Statement (Paper No. 14) filed on January 15, 2002 has been entered.

Response to Arguments

3. Applicant's response to the office action (Paper No.13) is fully considered and deemed persuasive.
4. With respect to the rejection made in the previous office action under 35 U.S.C. 112, second paragraph, applicants' amendment and arguments have been considered and the rejection is withdrawn herein.
5. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments with respect to claims 1-6, 10-12, 15-27, 30-38, 40-46 and 48-55 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 is indefinite over the recitation of "capable of hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to

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determine capability. That is, it is not clear whether the recited set of probes have the potential to hybridize or do in fact do hybridize the recited target nucleic acid which is to be detected.

Amendment of the claim to read, for example, "which hybridizes" would obviate this rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-27, 30-36, and 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Snitman et al. (USPN. 5,641,630).

Snitman et al. teach a method of detecting a target nucleic acid wherein Snitman et al. disclose that the method comprises hybridizing a nucleic acid target (double or single stranded) with a first probe (capture probe) and a second probe (signal probe) to which a reporter moiety is attached, forming a hybrid (DNA-DNA or RNA-RNA or DNA-RNA, and detecting the hybrid complex by binding an antibody which recognizes the hybrid (see column 5, lines 43-67, column 6, lines 1-6). Snitman et al. also teach (i) modifying capture probe with a ligand (see column 5, line 67, and column 6, lines 1-60); (ii) signal probe could be unlabeled (see column 6, lines 46-51); (iii) capture probe could be biotinylated (see column 6, 1-17); comprises single-stranded target DNA (see column 5, lines 43-62); hybrid could be captured onto a solid support (see column 7, lines 1-8); antibody could be labeled with alkaline phosphatase (see column 6, lines 52-67). Thus the disclosure of Snitman et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10-12, 15-26, 30-38, and 40-46, 48, 50-51, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snitman et al. (USPN. 5,641,630) and in view of Collins et al. (USPN. 6,232,462) and Shah et al. (USPN. 5,629,156).

Snitman et al. teach a method of detecting a target nucleic acid wherein Snitman et al. disclose that the method comprises hybridizing a nucleic acid target (double or single stranded) with a first probe (capture probe) and a second probe (signal probe) to which a reporter moiety is attached, forming a hybrid (DNA-DNA or RNA-RNA or DNA-RNA, and detecting the hybrid complex by binding an antibody which recognizes the hybrid (see column 5, lines 43-67, column 6, lines 1-6). Snitman et al. also teach (i) modifying capture probe with a ligand (see column 5, line 67, and column 6, lines 1-60); (ii) signal probe could be unlabeled (see column 6, lines 46-

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51); (iii) capture probe could be biotinylated (see column 6, 1-17); comprises single-stranded target DNA (see column 5, lines 43-62); hybrid could be captured onto a solid support (see column 7, lines 1-8); antibody could be labeled with alkaline phosphatase (see column 6, lines 52-67). However, Snitman et al. did not teach a blocker probe to remove excess non-hybridized capture probe.

Collins et al. teach a method for reducing nonspecific background signals in a hybridization assay wherein Collins et al. disclose that the method capture extenders (blocker probes) which have a region complementary to the target sequence and a second region complementary to a portion of a capture probe (see column 9, lines 33-67, column 10, lines 1-17, and column 23, lines 53-67).

Shah et al. teach a method of detecting a target nucleic acid wherein Shah et al. disclose that the method comprises hybridizing a target nucleic acid (DNA or RNA) to a capture probe and a detector probe (signal probe), adding a second capture probe (blocker probe) to remove excess non-hybridized capture probes (thereby removing background noise from the assay) and detecting the bound hybrid (see column 7, lines 17-29, column 3, lines 60-67, column 4, lines 1-51, and column 6, lines 30-57). Shah et al. also teaches immobilization of capture probe on to a solid support (see column 4, lines 29-32); The capture and release using first and second capture probes can be performed in either order (simultaneously or sequentially) (see column 6, lines 58-65). Further Shah et al. teach use of dA-tailed probes (bridge probes) which will bind to both target and dT derivitized supports such that the binding is stronger to the targets than the supports (see column 8, lines 44-54).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting a target nucleic acid as taught by Snitman et al. with the method of Collins et al. and Shah et al. which is applicable to remove un-hybridized capture probe because Snitman et al. states that 'one-step sandwich hybridization assay is less sensitive to contaminating materials in the sample, and leakage of the first probe from the support during hybridization occurs frequently and drastically diminishes the sensitivity of the assay' (see column 3, lines 49-61). One form of increasing the sensitivity of the hybridization assay, expressly motivated by Collins et al. and Shah et al. is to use a blocker probe to remove excess un-hybridized first probe to provide an hybridization assay with less background noise'. An ordinary practitioner would have been motivated to combine the method of Snitman et al. with the method of Shah et al. in order to achieve the expected advantage of highly sensitive and rapid hybridization method for the detection of a target nucleic acid.

No claims are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{SPC}
Suryaprabha Chunduru
April 5, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER